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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,364	04/12/2004	Robert Burgmeier	S63.2-10866-US01	3075
490 7590 01/07/2009 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER MEHTA, BHISMA	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 01/07/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/822,364	Applicant(s) BURGMEIER ET AL.	
	Examiner BHISMA MEHTA	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 is dependent on a cancelled claim (claim 3) and it is unclear which claim Applicant intended claim 11 to depend from. Thus, this makes it unclear as to the limitations being claimed in claim 11 and in claims 12-16 which all depend from claim 11. For the purpose of examination of the claims, claim 11 will be treated as being dependent from claim 1.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by Zamore (U.S. Patent Application No. 2004/0093008). Zamore discloses a dilatation balloon with

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a first and second waist portion, a first and second cone portion, and a body portion where the balloon is formed of a first polymeric composition that forms a first layer (A) and a second layer (B) on at least one of the cone portions of the balloon formed from a second composition which is crosslinked to form a compression region.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 6-9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamore in view of Pederson, Jr. et al (U.S. Patent Application Publication No. 2004/0073250). Zamore discloses a dilatation balloon with waist portions, cone portions, and a body portion where the balloon is formed of a first polymeric composition forming a first layer (A) and a second layer (B) is formed on at least a portion of the first layer. The second layer comprises a second polymeric composition which is crosslinked to form a compression region on at least a portion of the balloon. Zamore discloses that the second polymeric composition is crosslinked on at least a portion of the waist portions, the cone portions, or both (paragraph [0300]). Zamore discloses that the first polymeric composition of the first layer is a thermoplastic polymer material that is compatible with the first polymeric composition but which is crosslinkable when exposed to crosslinking energy (paragraph [0300]). In paragraph

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[0088], Zamore discloses the first polymeric composition as being a thermoplastic material including polyolefin or polyethylene terephthalate. In paragraphs [0057] and [0088], Zamore disclose the second polymeric composition being a thermoplastic material which is considered to be a thermoset material after crosslinking has occurred and can be selected from the group of polyolefin or polyethylene.

Zamore discloses the balloon substantially as claimed. However, Zamore is silent to the specifics of the body portion of the balloon being uncrosslinked. Pederson, Jr. et al disclose a dilatation balloon with waist portions (16), cone portions (14), and a body portion (12) where the balloon may be comprised of a combination of materials and may be multilayered (paragraph [0043]). In paragraph [0029], Pederson, Jr. et al disclose that the body portion of the balloon engages a patient's vessel wall or the inner diameter of a stent when the balloon is inflated. Pederson, Jr. et al also disclose that the balloon material may be crosslinked or uncrosslinked depending on the material used for the balloon and the desired characteristics for the specific application (paragraph [0044]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the body portion of the balloon of Zamore as an uncrosslinked portion as taught by Pederson, Jr. et al as both Zamore and Pederson, Jr. et al disclose a multilayered balloon where the balloon material can be crosslinked or uncrosslinked and Pederson, Jr. et al teach that it is well known to use a uncrosslinked material for the balloon if desired for a specific application and also indicate that the body portion of the balloon, which can comprise the majority of the length of the balloon, is the portion that engages the vessel wall or stent. Thus, the

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body portion could be chosen to be uncrosslinked depending on the specific application of the balloon.

7. Claims 1, 5-9, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al (U.S. Patent No. 5,344,400) in view of Zamore (U.S. Patent Application No. 2004/0093008) and in view of Pederson, Jr. et al. Kaneko et al disclose a dilatation balloon with waist portions (10, 12), cone portions, and a body portion where the balloon is formed of a first polymeric composition forming a first layer (18) and a second layer (16) is formed on at least a portion of the first layer of the balloon. The second layer comprises a second polymeric composition (16). Kaneko et al disclose the second polymeric composition as being selected from the group of olefins or comprising polyethylene. Kaneko et al also disclose a tie layer (17) between a first layer (18) and the second layer (16). In lines 14-26 of column 5, Kaneko et al disclose the first layer or the first polymeric composition as a polyolefin or a polyester. In lines 53-68 of column 5, Kaneko et al disclose a tie layer between the balloon and the catheter shaft. As to claim 17, Kaneko et al disclose a dilatation balloon with a first and second waist portion (10, 12), a first and second cone portion, and a body portion where the balloon is formed from a first polymeric composition that forms a first layer (18) and a second layer (16) on at least one of the first and second cone portions of the balloon formed from a second composition.

Kaneko et al disclose the balloon substantially as claimed. Even though Kaneko et al disclose the second layer being formed on at least a portion of the first layer and the second composition being selected from the group of olefins or comprising

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polyethylene (lines 47-53 of column 6), Kaneko et al are silent on the specifics of the second polymeric composition being crosslinked to form a compression region. Zamore discloses a dilatation balloon with a first layer and a second layer on at least a portion of the first layer where the second polymeric composition is crosslinked. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the second layer of Kaneko et al from a polymeric composition which is crosslinkable as taught by Zamore as both Kaneko et al and Zamore teach dilatation balloons with multiple layers and Zamore teaches that it is well known to provide a crosslinkable second layer in order to form balloons with varying degrees of compliancy so that the balloons can be manufactured with compliance characteristics varying from high compliance to low compliance while still having the desired burst strength. As to claims 7 and 9, even though Kaneko et al disclose the second composition as polyethylene (lines 47-53 of column 6), Kaneko et al are silent on the first polymeric composition comprising a polyether block amide. Zamore discloses a balloon where the first layer comprises a first polymeric composition which is formed of a polyether block amide and a second layer comprising a second polymeric composition which is polyethylene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the first polymeric composition of Kaneko et al a polyether block amide as taught by Zamore as both Kaneko et al and Zamore teach balloons with multiple layers and Zamore teaches that it is well known to use polyether block amide for the first layer.

Kaneko et al and Zamore disclose the balloon substantially as claimed.

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However, Kaneko et al and Zamore are silent to the specifics of the body portion of the balloon being uncrosslinked. Pederson, Jr. et al disclose a dilatation balloon with waist portions (16) , cone portions (14), and a body portion (12) where the balloon may be comprised of a combination of materials and may be multilayered (paragraph [0043]). .

In paragraph [0029], Pederson, Jr. et al disclose that the body portion of the balloon engages a patient's vessel wall or the inner diameter of a stent when the balloon is inflated. Pederson, Jr. et al also disclose that the balloon material may be crosslinked or uncrosslinked depending on the material used for the balloon and the desired characteristics for the specific application (paragraph [0044]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the body portion of the balloon of Kaneko et al and Zamore as an uncrosslinked portion as taught by Pederson, Jr. et al as Kaneko et al, Zamore, and Pederson, Jr. et al all disclose a multilayered balloon where the balloon material can be crosslinked or uncrosslinked and Pederson, Jr. et al teach that it is well known to use a uncrosslinked material for the balloon if desired for a specific application and also indicate that the body portion of the balloon, which can comprise the majority of the length of the balloon, is the portion that engages the vessel wall or stent. Thus, the body portion could be chosen to be uncrosslinked depending on the specific application of the balloon.

8. Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamore in view of Pederson, Jr. et al as applied to claims 1 and 11 above, and further in view of Kaneko et al. Zamore and Pederson, Jr. et al disclose the balloon substantially as claimed. However, Zamore and Pederson, Jr. et al are silent on a tie layer between

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the first layer and the second layer and a tie layer between the balloon and the catheter shaft. Kaneko et al disclose a tie layer (17) between a first layer (18) and the second layer (16) and a tie layer between the balloon and the catheter shaft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide between the first layer and the second and between the balloon and the catheter shaft of Zamore a tie layer as taught by Kaneko et al as both Zamore and Kaneko et al teach balloons with multiple layers and Kaneko et al teach that it is well known to provide a tie layer to allow for good adhesion of the first layer to the second layer and of the balloon to the catheter shaft.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zamore in view of Pederson, Jr. et al as applied to claim 6 above, and further in view of Smith et al (U.S. Patent No. 6,083,587). Zamore and Pederson, Jr. et al disclose the balloon substantially as claimed. However, Zamore and Pederson, Jr. et al are silent on the specifics of a tie layer comprising polyethylene modified with at least one member. Smith et al disclose multi-layered polymer structures for medical devices where a tie layer is formed between a first layer and a second layer. In lines 1-22 of column 5, Smith et al disclose the tie layer as comprising a polyethylene modified with maleic anhydride. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide between the first and second layers of Zamore a tie layer comprising polyethylene modified with maleic anhydride as taught by Smith et al as both Zamore and Smith et al teach medical devices with multiple layers and Smith et al teach that it is well known to use a tie layer comprising polyethylene modified with

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maleic anhydride between the multiple layers for good adhesion of the first layer to the second layer.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al in view of Zamore and in view of Pederson, Jr. et al. as applied to claim 6 above, and further in view of Smith et al (U.S. Patent No. 6,083,587). Kaneko et al, Zamore, and Pederson, Jr. et al disclose the balloon substantially as claimed. Even though Kaneko et al disclose the tie layer, Kaneko et al are silent on the specifics of the tie layer comprising polyethylene modified with at least one member. Smith et al disclose multi-layered polymer structures for medical devices where a tie layer is formed between a first layer and a second layer. In lines 1-22 of column 5, Smith et al disclose the tie layer as comprising a polyethylene modified with maleic anhydride. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the tie layer of Kaneko et al a polyethylene modified with maleic anhydride as taught by Smith et al as both Kaneko et al and Smith et al teach medical devices with multiple layers and tie layers between the multiple layers and Smith et al teach that it is well known to use a polyethylene modified with maleic anhydride for the tie layer.

11. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamore in view of Pederson, Jr. et al and in view of Kaneko et al as applied to claim 13 above, and further in view of Samuelson et al (U.S. Patent No. 6,464,683). Zamore, Pederson, Jr. et al, and Kaneko et al disclose the balloon substantially as claimed. Even though Kaneko et al disclose the tie layer, Kaneko et al are silent on the specifics

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of the tie layer comprising a crosslinking inhibitor or the tie layer being formed from a polymeric composition having a lower melting temperature than the first polymeric composition. Samuelson et al disclose multi-layered polymer structures for medical devices where a tie layer (14) is formed between a first layer (12) and a second layer (16). In lines 13-67 of column 7 and in lines 1-14 of column 8, Samuelson et al disclose the tie layer as comprising a crosslinking inhibitor and as having a lower melting temperature than the first polymeric composition of the first layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the tie layer of Kaneko et al a crosslinking inhibitor with a lower melting temperature than the first polymeric composition of the first layer as taught by Samuelson et al as both Kaneko et al and Samuelson et al teach medical devices with multiple layers and tie layers between the multiple layers and Samuelson et al teach that it is well known to use a crosslinking inhibitor for the tie layer and to use a tie layer which has a lower melting temperature than the first layer of the device.

12. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al in view of Zamore and in view of Pederson, Jr. et al as applied to claim 13 above, and further in view of Samuelson et al (U.S. Patent No. 6,464,683). Kaneko et al, Zamore, and Pederson, Jr. et al disclose the balloon substantially as claimed. Even though Kaneko et al disclose the tie layer, Kaneko et al are silent on the specifics of the tie layer comprising a crosslinking inhibitor or the tie layer being formed from a polymeric composition having a lower melting temperature than the first polymeric composition. Samuelson et al disclose multi-layered polymer structures for medical

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devices where a tie layer (14) is formed between a first layer (12) and a second layer (16). In lines 13-67 of column 7 and in lines 1-14 of column 8, Samuelson et al disclose the tie layer as comprising a crosslinking inhibitor and as having a lower melting temperature than the first polymeric composition of the first layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the tie layer of Kaneko et al a crosslinking inhibitor with a lower melting temperature than the first polymeric composition of the first layer as taught by Samuelson et al as both Kaneko et al and Samuelson et al teach medical devices with multiple layers and tie layers between the multiple layers and Samuelson et al teach that it is well known to use a crosslinking inhibitor for the tie layer and to use a tie layer which has a lower melting temperature than the first layer of the device.

13. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al in view of Zamore. Kaneko et al disclose a dilatation balloon with a first and second waist portion (10, 12), a first and second cone portion, and a body portion where the balloon is formed from a first polymeric composition that forms a first layer (18) and a second layer (16) on at least one of the first and second cone portions of the balloon formed from a second composition. Kaneko et al disclose the balloon substantially as claimed. Even though Kaneko et al disclose the second layer being formed on at least a portion of the first layer and the second composition being selected from the group of olefins or comprising polyethylene (lines 47-53 of column 6), Kaneko et al are silent on the specifics of the second polymeric composition being crosslinked to form a compression region. Zamore discloses a dilatation balloon with a first layer and a

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second layer on at least a portion of the first layer where the second polymeric composition is crosslinked. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the second layer of Kaneko et al from a polymeric composition which is crosslinkable as taught by Zamore as both Kaneko et al and Zamore teach dilatation balloons with multiple layers and Zamore teaches that it is well known to provide a crosslinkable second layer in order to form balloons with varying degrees of compliancy so that the balloons can be manufactured with compliance characteristics varying from high compliance to low compliance while still having the desired burst strength.

Response to Arguments

14. Applicant's arguments with respect to claims 1 and 5-16 have been considered but are moot in view of the new ground(s) of rejection.

15. Applicant's arguments filed October 13 2008 with regards to the prior art rejection of claim 17 have been fully considered but they are not persuasive. Applicant's arguments in lines 14-19 of page 9 are not persuasive because claim 1 is argued to be not anticipated by Zamore with regards to the limitation of the body portion being uncrosslinked and this limitation is not in claim 17, and the arguments for claim 1 do not pertain to claim 17. For the same reason, Applicant's arguments in lines 24-27 of page 10 and in line 17 of page 11 to line 13 of page 12 are not persuasive.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

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Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767